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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	8

DATE MAILED: 03/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/590,968	Applicant(s) RAY ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-25 are pending in the instant application.

Election/Restriction

Claims 16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that no benefit is derived from maintaining the restriction requirement because the two inventions are closely related and would require common areas of search and consideration. This is not found persuasive because the searches and considerations required for properly examining Group I, drawn to compositions and methods comprising nucleic acids and Group II, drawn to proteins, would not be coextensive, despite some overlap.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7, 8, 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because:

Claims 4, 7, 8, 18, 20, 22, 24 and 25 recite the limitation" DNA molecule of claim 1" in lines 2-3 of the claims. There is insufficient antecedent basis for this limitation in the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-15 and 18-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions and methods for modulating the fertility or fecundity of a plant (and transgenic plants and plant cells generated from the methods) comprising transducing the plant with a nucleic acid molecule encoding a short integuments1 protein, including a nucleotide sequence which is at least 55% similar to SEQ ID NO. 1, or an antisense derived therefrom.

The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising nucleic acid molecules encoding a short

integuments1 protein. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. One of skill in the art would reasonably conclude that the disclosure fails to adequately describe or provide a representative number of species to describe the genus comprising nucleic acids encoding short integuments 1 proteins, including the nucleic acids which are at least 55% similar to SEQ ID NO: 1, or those representative species identified by their ability to hybridize in hybridization buffer comprising 0.9M sodium citrate buffer at 45°C. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Thus, Applicant was not in possession of the claimed genus.

Claims 1-15 and 18-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule of SEQ ID NO: 1, does not reasonably provide enablement for isolated nucleic acid molecules encoding any and/or all short integuments1 proteins, nor any methods modulating the fertility of any plants, nor methods of generating transgenic plants comprising the transduction of plant cells with a nucleic acid molecule encoding a short integuments1 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to compositions and methods for modulating the fertility or fecundity of any plant, and the generation of transgenic plants, comprising the transduction of

plant cells with isolated nucleic acid molecules encoding any short integuments1 protein, including SEQ ID NO: 1, or any nucleic acids which share at least 55% similarity with SEQ ID NO: 1 (as determined by basic Blast), or any nucleic acids which are found to hybridize in hybridization buffer comprising 0.9M sodium citrate buffer at 45°C.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

The amount of direction or guidance presented in the specification AND the presence or absence of working examples. Applicants have not provided guidance in the specification toward a method of modulating the fertility or fecundity of any and/or all plants, or generating any transgenic plants with altered fertility characteristics comprising the transduction of plants or plant cells with nucleic acids encoding any short integuments1 protein, or antisense derived therefrom.

The specification teaches the disclosure and alignment (using Blast) of nucleotides of SEQ ID NO: 1 with a previously disclosed SIN1 gene. The specification also teaches a predicted amino acid sequence (SEQ ID NO: 2) derived from a purported open reading frame of SEQ ID NO: 1. The specification fails to teach the expression of a polypeptide or protein of SEQ ID NO: 2 in vitro or in vivo. The specification as filed fails to teach the transduction of any plants with SEQ ID NO: 1 or antisense derived therefrom, whereby fertility or fecundity has been modulated in the transduced host. The specification fails furthermore to teach the generation of any transgenic plants with such fertility or fecundity modulations following the stable transduction

with any nucleic acid purportedly encoding a short integuments1 protein. One skilled in the art would not accept on its face the examples given in the specification of a predicted open reading derived from SEQ ID NO: 1 as being correlative or representative of the expression of any and/or all representatives of the genus comprising short integuments1 proteins, and further whereby fertility or fecundity modulation is achieved in any and/or all plants comprising transduction with any representative species of the claimed genus, or antisense derived therefrom, in view of the lack of guidance in the specification and known unpredictability associated with the ability to produce a desired characteristic in a plant in vivo, or to produce a transgenic plant based on a predicted phenotype to be obtained from a purported translation product, which translation product is derived from a nucleotide sequence. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with predicted fertility or fecundity effects provided by antisense administered, and specifically regarding the instant genus comprising short integuments1 proteins, including those encoded by any nucleic acids which share at least 55% similarity with SEQ ID NO: 1, or are hybridizable with SEQ ID NO: 1 in a hybridization buffer comprising 0.9M sodium citrate buffer at 45°C..

The breadth of the claims and the quantity of experimentation required. The breadth of the claims is very broad. The claims are drawn to compositions and methods for modulating the fertility or fecundity of any plant, and the generation of transgenic plants, comprising the transduction of plant cells with isolated nucleic acid molecules encoding any short integuments1 protein, including SEQ ID NO: 1, or any nucleic acids which share at least

55% similarity with SEQ ID NO: 1 (as determined by basic Blast), or any nucleic acids which are found to hybridize in hybridization buffer comprising 0.9M sodium citrate buffer at 45°C. In order to practice the invention over the scope claimed, it would require undue trial and error and undue experimentation beyond which is taught in the specification to practice the invention drawn to the generation of plants with altered fertility following the transduction with nucleic acids encoding any short integuments1 protein The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of a representative number of species comprising nucleic acids encoding short integuments1 proteins, including those which share at least 55% similarity with SEQ ID NO: 1, or hybridize with SEQ ID NO: 1 in a hybridization buffer comprising 0.9M sodium citrate buffer at 45°C, whereby fertility or fecundity is modulated following transduction with a representative number of species of this genus, or antisense derived therefrom. Since the specification fails to provide any particular guidance for the successful modulation in fertility or fecundity following transduction with any nucleic acid encoding a short integuments1 protein or antisense, and since determination of these factors for a particular short integuments1 protein in an appropriate plant host is highly unpredictable, it would require undue experimentation to practice the invention over the scope claimed.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Ecker.

Ecker teaches a nucleic acid molecule of SEQ ID NO: 1, encoding a short integuments1 protein of SEQ ID NO: 2 (See the accompanying alignment data between accession AC007323 and SEQ ID Nos: 1 and 2).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

March 22, 2002

Jane Zara

TC1600